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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,661	03/26/2001	Jane Osbourn	84633-000100US	9792

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EXAMINER
EPPERSON, JON D

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary File Copy	Application No. 09/817,661	Applicant(s) OSBOURN ET AL.	
	Examiner Jon D Epperson	Art Unit 1639	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The fax number is (703) 308-4315. A fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Andrew Wang, Supervisory Patent Examiner, at (703) 306-3217. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Please note: The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1639**.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-14 and 21-23, drawn to a method for "obtaining a specific binding pair (sbp) that binds a complementary sbp member of interest", classified variously in class 435, subclass 4, 6, 7.1, 69.1.

   II. Claims 15-20 and 24, drawn to a method for "formulating the product into a composition comprising at least one additional component [e.g., excipient or carrier]", classified variously in class 424, subclass 455; class 514, subclass 960, subclass 947.

   III. Claims 25-26, drawn to a product described as a "nucleic acid construct" or a "library or population of RNA molecules", classified variously in class 536, subclass 23.1, 23.4, 24.2, 23.72.

IV. Claims 27-28, drawn to a product described as a "population of viral particles", classified variously in class 435, subclass 320.1, class 930, and subclass 220.

V. Claims 29-30, drawn to a product described as an "expression system", classified variously in class 435, subclass 320.1; class 424, subclass 196.11.

2. The inventions are distinct, each from the other because of the following reasons:

3. Groups I-V represent separate and patentably distinct inventions. Groups I-II are drawn to different methods and Groups III-V are drawn to different products (i.e., e.g., which are directed to different purposes, use different materials, recite different method or process steps for the preparation of different product(s), screening of different characteristics, such as different binding affinities, different biochemical reaction conditions, etc. or lead to different final results). Therefore, the groups that describe these products and methods have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches. Art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Each group will support separate patents.

4. Groups I and II represent separate and patentably distinct methods. The methods are distinct because they use different steps, require different reagents and/or will produce different results. In this case, the method of Group II employs an extra step i.e., "formulating the product

into a composition comprising at least one additional component", which is not required by the method of Group I. As a result, Group II requires a different reagent (excipients and carriers) that are not required by Group I. In addition, since Group I does not utilize exipients and carriers, Group I will produce different results than Group II in situations where these reagents are required. Furthermore, the Groups I and II can be classified into different classes and subclasses (see paragraph 1 above). Therefore, Groups I and II have different issues regarding patentability and enablement and represent patentably distinct subject matter.

5. Furthermore, Groups III-V represent patentably distinct products. Groups III-V represent separate and patentably distinct products because they differ in respect to their properties, their use and the synthetic methodology for making them. For example, Group III is drawn to a "nucleic acid construct", which requires different reagents and/or materials than Groups I and II. Likewise, Group II is drawn to a "population of viral particles", which requires different reagents and/or materials than Groups I and III. Therefore, art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Consequently, Groups III-V have different issues regarding patentability and enablement and represent patentably distinct subject matter.

6. Finally, Groups I-V represent separate and distinct inventions because Group I-I claims methods while Group III-V claims products. However, if applicant were to argue that any of the Groups were somehow related as product and process of use, the inventions can be shown to be

distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, (2) the product(s) as claimed (i.e., Groups III-V) can be used in materially different process of using that product (MPEP § 806.05(h)), for example, the products can be used in the method of Group I or the method of Group II.

7. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and products would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

8. This application contains claims directed to patentably distinct species of the claimed invention for Groups I-IV. Election is required as follows.

9. If applicant elects the invention of Groups I, applicant is required to elect from the following patentably distinct species. Claim 1 is generic.

Subgroup 1: Species of specific binding pair (see claim 1)

Applicant must elect, for the purposes of search, a ***single species*** of specific binding pair e.g., scFv antibody molecules (see specification, page 19, line 15).

Subgroup 2: Species of mRNA (see claim 1)

Applicant must elect, for the purposes of search, a ***single species*** of mRNA. Applicant must disclose whether the single elected species contains a midvariant (MDV) RNA (see claim 2), a gly-ser tether wherein the number of gly-ser units is specified (see claims 3-4), the sequence for encapsidation e.g., HA-OAS 2 (see specification, page 32, lines 28-31). Applicant should also indicate any primers that were used to make the species.

Subgroup 3: Species of coat protein (see claim 1)

Applicant must elect, for the purposes of search, a ***single species*** of coat protein e.g., U1 TMV (see specification, page 33, lines 30-34).

Subgroup 4: Species of replication (see claim 1)

Applicant must elect, for the purposes of search, a ***single species*** of replication e.g., RT-PCR, QB-replicase (see specification, page 18, lines 6-12; see also example 5).

Subgroup 5: Species of providing mRNA (see claim 9)

Applicant must elect, for the purposes of search, a ***single species*** of method for providing mRNA e.g., method steps of claim 9.

Subgroup 6: Species of ribosome source (see claim 1)

A. Prokaryotic
B. Eukaryotic

Applicant must elect, for the purposes of search, a ***single species*** of ribosome source. Please pick A or B above.

Subgroup 7: Species of glutathione addition (see claim 5)

A. Glutathione added
B. Glutathione not added

Applicant must elect, for the purposes of search, a ***single species*** of method for glutahione addition. Please pick A or B above. If applicant picks A, please also indicate the ratio of oxidized and reduced glutathione.

Subgroup 8: Species of protein disulphide isomerase addition (see claim 5)

A. Disulphide isomerase added
B. Disulphide isomerase not added

Applicant must elect, for the purposes of search, a ***single species*** of method for protein disulphide isomerase addition. Please pick A or B above.

Subgroup 9: Species of heparin addition (see claim 5)

A. Heparin added
B. Heparin not added

Applicant must elect, for the purposes of search, a ***single species*** of method for heparin addition. Please pick A or B above.

Subgroup 10: Species of method for mutation (see claim 21)

Applicant must elect, for the purposes of search, a ***single species*** of method for mutation e.g., see figure 7.

10. If applicant elects the invention of Group II, applicant is required to elect from the following patentably distinct species. Claim 15 is generic.

Subgroup 1: Species of specific binding pair (see claim 1)

Applicant must elect, for the purposes of search, a ***single species*** of specific binding pair e.g., scFv antibody molecules (see specification, page 19, line 15).

Subgroup 2: Species of mRNA (see claim 1)

Applicant must elect, for the purposes of search, a ***single species*** of mRNA. Applicant must disclose whether the single elected species contains a midvariant (MDV) RNA (see claim 2), a gly-ser tether wherein the number of gly-ser units is specified (see claims 3-4), the sequence for encapsidation e.g., HA-OAS 2 (see specification, page 32, lines 28-31). Applicant should also indicate any primers that were used to make the species.

Subgroup 3: Species of coat protein (see claim 1)

Applicant must elect, for the purposes of search, a ***single species*** of coat protein e.g., U1 TMV (see specification, page 33, lines 30-34).

Subgroup 4: Species of replication (see claim 1)

Applicant must elect, for the purposes of search, a ***single species*** of replication e.g., RT-PCR, QB-replicase (see specification, page 18, lines 6-12; see also example 5).

Subgroup 5: Species of providing mRNA (see claim 9)

Applicant must elect, for the purposes of search, a ***single species*** of method for providing mRNA e.g., method steps of claim 9.

Subgroup 6: Species of ribosome source (see claim 1)

A. Prokaryotic
B. Eukaryotic

Applicant must elect, for the purposes of search, a ***single species*** of ribosome source. Please pick A or B above.

Subgroup 7: Species of glutathione addition (see claim 5)

A. Glutathione added
B. Glutathione not added

Applicant must elect, for the purposes of search, a ***single species*** of method for glutahione addition. Please pick A or B above. If applicant picks A, please also indicate the ratio of oxidized and reduced glutathione.

Subgroup 8: Species of protein disulphide isomerase addition (see claim 5)

A. Disulphide isomerase added
B. Disulphide isomerase not added

Applicant must elect, for the purposes of search, a ***single species*** of method for protein disulphide isomerase addition. Please pick A or B above.

Subgroup 9: Species of heparin addition (see claim 5)

A. Heparin added
B. Heparin not added

Applicant must elect, for the purposes of search, a ***single species*** of method for heparin addition. Please pick A or B above.

Subgroup 10: Species of additional component (see claim 15)

Applicant must elect, for the purposes of search, a ***single species*** of additional component.

Subgroup 11: Species of additional amino acids (see claims 16-17)

Applicant must elect, for the purposes of search, a ***single species*** of additional amino acids e.g., antibody constant region.

Subgroup 12: Species of expression system (see claim 22)

Applicant must elect, for the purposes of search, a ***single species*** of expression system e.g., rabbit reticulocyte lysate (see specification page 19, line 6).

11. If applicant elects the invention of Group III, applicant is required to elect from the following patentably distinct species. Claim 25 is generic.

Subgroup 1: Species of nucleic acid construct (see claim 25)

Applicant must elect, for the purposes of search, a ***single species*** of nucleic acid construct. Applicant must disclose whether construct is RNA or DNA. Applicant must also disclose a specific RNA polymerase binding site, ribosome binding site, initiation codon, conding sequence for fusion protein, tether, sequence for encapsidation of mRNA in viral coat.

12. If applicant elects the invention of Group IV, applicant is required to elect from the following patentably distinct species. Claim 27 is generic.

Subgroup 1: Species of nucleic acid construct (see claim 27)

Applicant must elect, for the purposes of search, a ***single species*** of nucleic acid construct. Applicant must disclose whether construct is RNA or DNA. Applicant must also disclose a specific RNA polymerase binding site, ribosome binding site, initiation codon, conding sequence for fusion protein, tether, sequence for encapsidation of mRNA in viral coat.

Subgroup 2: Species of coat protein (see claim 27)

Applicant must elect, for the purposes of search, a ***single species*** of coat protein e.g., U1 TMV (see specification, page 33, lines 30-34).

13. If applicant elects the invention of Group V, applicant is required to elect from the following patentably distinct species. Claim 29 is generic.

Subgroup 1: Species of nucleic acid construct (see claim 29)

Applicant must elect, for the purposes of search, a ***single species*** of nucleic acid construct. Applicant must disclose whether construct is RNA or DNA. Applicant must also disclose a specific RNA polymerase binding site, ribosome binding site, initiation codon, conding sequence for fusion protein, tether, sequence for encapsidation of mRNA in viral coat.

Subgroup 2: Species of coat protein (see claim 29)

Applicant must elect, for the purposes of search, a ***single species*** of coat protein e.g., U1 TMV (see specification, page 33, lines 30-34).

Subgroup 3: Species of expression system (see claim 29)

Applicant must elect, for the purposes of search, a ***single species*** of expression system e.g., rabbit reticulocyte lysate (see specification page 19, line 6).

14. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter.

Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

15. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

16. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a a rejection under 35 U.S.C. 103(a) of the other invention.

17. Applicant is advised that a reply to this requirement ***must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added***. An argument that a claim is allowable or that all claims are generic is considered ***nonresponsive*** unless accompanied by an election.

18. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, ***applicant must indicate which are readable upon the elected species***. MPEP § 809.02(a).

19. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

20. Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

21. Applicant is also reminded that a 1 – month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (703) 308-2423. The examiner can normally be reached Monday through Friday from 8:30 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-2439.

Jon D. Epperson, Ph.D.
February 23, 2003

BENNETT CELSA
PRIMARY EXAMINER